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Docket Number 5047 CON

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Nick Wan et al.  
Serial Number : 10/800,602  
Examiner : Not Yet Assigned  
Art Unit : 1636  
Filed : March 15, 2004  
For : EXPRESSION SYSTEM FOR  
RECOMBINANT PROTEINS

Commissioner for Patents  
United States Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313-1450

I certify that this document is being deposited on January 27, 2005 with the United States Postal Service as Express Mail No. EV 386751943 under 37.C.F.R. 1.8 and is addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 .

Deborah. A. Gunkel  
Printed name of person mailing correspondence

*Deborah A. Gunkel*  
Signature of person mailing correspondence

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 C.F.R. § 1.97(b)**

Sir:

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), Applicants bring to the attention of the Examiner the documents listed on the attached Form PTO-A820 (also form PTO-1449). This Information Disclosure Statement is being filed before the mailing of the first Office Action on the merits. Thus, pursuant to § 1.97(b)(3), no fee is required.

Also made part of the attached Form PTO-1449 are references listed on the attached International Search Report.

Copies of the listed documents are attached. Applicants respectfully request that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached form.

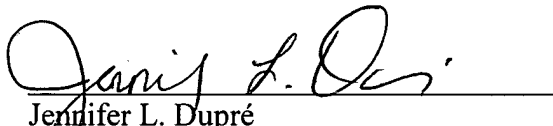
This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art". If the Examiner applies any of the documents as prior art against any claims in the application and Applicants determine that the cited documents do not constitute "prior art" under United States law, Applicants reserve the right to present to the office the relevant facts and law regarding the appropriate status of such documents.

Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

The Commissioner is hereby authorized to charge Deposit Account No. 07-1074 for any fees which may be due or credit any overpayment. A duplicate copy of this paper is enclosed.

Respectfully submitted,

January 27, 2005

  
Jennifer L. Dupré  
Registration No.: 41,722  
Genzyme Corporation  
500 Kendall Street  
Cambridge, MA 02142  
Tel.: (617) 768-6523  
Fax: (617) 252-7553

**TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT**

(Under 37 CFR 1.97(b) or 1.97(c))

Docket No.

5047 CON

In Re Application Of: Nick Wan et al.

JAN 27 2005

Application No.

10/800,602

Filing Date

March 15, 2004

Examiner

Not Yet Assigned

Customer No.

24536

Group Art Unit

1636

Confirmation No.

1807

Title: **EXPRESSION SYSTEM FOR RECOMBINANT PROTEINS**

Address to:

Commissioner for Patents

P.O. Box 1450

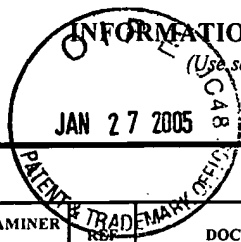
Alexandria, VA 22313-1450

**37 CFR 1.97(b)**

1. ☒ The Information Disclosure Statement submitted herewith is being filed within three months of the filing of a national application other than a continued prosecution application under 37 CFR 1.53(d); within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; before the mailing of a first Office Action on the merits, or before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

**37 CFR 1.97(c)**

2. ☐ The Information Disclosure Statement submitted herewith is being filed after the period specified in 37 CFR 1.97(b), provided that the Information Disclosure Statement is filed before the mailing date of a Final Action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an Action that otherwise closes prosecution in the application, and is accompanied by one of:
- ☐ the statement specified in 37 CFR 1.97(e);
- OR**
- ☐ the fee set forth in 37 CFR 1.17(p).



## INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

JAN 27 2005

Docket Number (Optional)

5047 CON

Application Number

10/800,602

Applicant(s)

Nick Wan et al.

Filing Date

March 15, 2004

Group Art Unit

1636

## U.S. PATENT DOCUMENTS

*EXAMINER INITIAL	REF	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
		5,549,892	8/27/1996	Friedman et al.	424	94.61	

## FOREIGN PATENT DOCUMENTS

	REF	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
							YES	NO
		EP 0 256 421 A2	02/24/1988	Europe				

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

		BEUTLER ET AL.: "Polymorphisms in the Human Glucocerebrosidase Gene." GENOMICS, vol. 12, no. 4, (1992), pages 795-800.
		CREGG JAMES M ET AL: "Production of foreign proteins in the yeast Pichia pastoris." CANADIAN JOURNAL OF BOTANY, vol. 73, no. SUPPL. 1 SECT. E-H, (1995), pages S891-S897.

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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(Use several sheets if necessary)

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INITIAL

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

GOODRICK J C ET AL: "High Level Expression and Stabilization of Recombinant Human Chitinase Produced in a Continuous Constitutive Pichia pastoris Expression System." BIOTECHNOLOGY AND BIOENGINEERING, vol. 74, no. 6, September 20, 2001, pages 492-497.

Invitrogen Catalog (1998) pages 19-22.

MERKLE R K ET AL: "Cloning, expression, purification, and characterization of the murine lysosomal acid alpha-mannosidase" BBA - GENERAL SUBJECTS, ELSEVIER SCIENCE PUBLISHERS, NL, vol. 1336, no. 2, 27 August 1997 (1997-08-27), pages 132-146.

SBERNA G ET AL: "Advantages of the Methylotrophic Yeast Pichia pastoris for High-level Expression and Purification of Heterologous Proteins" AUSTRALASIAN BIOTECHNOLOGY, vol. 6, no. 2, April 1996 (1996-04), pages 82-87.

SCHILLING, J.C.: "Scale-Up of a High Cell Density Continuous Culture with Pichia pastoris X-33 for the Constitutive Expression of rh-Chitinase", BIOTECHNOLOGY PROGRESS, vol. 17, no. 4, 2000, pages 629-633.

SHERIFF S ET AL: "Characterization of Lysosomal Acid Lipase by Site-directed Mutagenesis and Heterologous Expression", JOURNAL OF BIOLOGICAL CHEMISTRY, AMERICAN SOCIETY OF BIOLOGICAL CHEMISTS, BALTIMORE, MD, US, vol. 270, no. 46, 17 November 1995 (1995-11-17), pages 27766-27772.

WATERHAM H R ET AL: "Isolation of the Pichia pastoris glyceraldehyde-3-phosphate dehydrogenase gene and regulation and use of its promoter", GENE: AN INTERNATIONAL JOURNAL ON GENES AND GENOMES, ELSEVIER SCIENCE PUBLISHERS, BARKING, GB, vol. 186, no. 1, 20 February 1997 (1997-02-20), pages 37-44.

EXAMINER

DATE CONSIDERED

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